



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the Federal Register of April 25, 2014 (79 FR 22995). The amendment is being made to reflect a change in the Agenda portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [PDAC@fda.hhs.gov](mailto:PDAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 25, 2014, FDA announced that a meeting of the Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee would be held on

October 16, 2014. On page 22996, in the first column, the Agenda portion of the document is changed to read as follows:

Agenda: The committees will discuss safety data from observational studies and a meta-analysis of randomized controlled clinical trials that have been conducted since the original signal of serious neuropsychiatric adverse events with CHANTIX (varenicline tartrate tablets, NDA 21928, Pfizer, Inc.) emerged. The committees will also discuss whether any action needs to be taken with regard to how this risk is described in product labeling.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: September 9, 2014

Leslie Kux,

Assistant Commissioner for Policy.